# **Complete Summary**

#### **GUIDELINE TITLE**

Estrogen and progestogen therapy in postmenopausal women.

# BIBLIOGRAPHIC SOURCE(S)

Estrogen and progestogen therapy in postmenopausal women. Fertil Steril 2004 Jan; 81(1): 231-41. [75 references] PubMed

#### **GUIDELINE STATUS**

This is the current release of the guideline.

# COMPLETE SUMMARY CONTENT

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## SCOPE

#### DISEASE/CONDITION(S)

Estrogen and progestogen therapy

**GUIDELINE CATEGORY** 

Management Prevention

CLINICAL SPECIALTY

Family Practice Internal Medicine Obstetrics and Gynecology

**INTENDED USERS** 

## Physicians

## GUIDELINE OBJECTIVE(S)

To present recommendations for the use of hormone therapy to treat or prevent problems associated with the decline of estrogen production by the ovaries after menopause

## TARGET POPULATION

Postmenopausal women

#### INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Estrogen alone therapy (EP)
- 2. Estrogen combined with progesterone therapy (E/PT)

## MAJOR OUTCOMES CONSIDERED

- Cessation of symptoms associated with estrogen depletion
- Adverse effects associated with hormone therapy

## **METHODOLOGY**

#### METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The Practice Committee of the American Society for Reproductive Medicine and the Board of Directors of the American Society for Reproductive Medicine approved this report.

#### RECOMMENDATIONS

## MAJOR RECOMMENDATIONS

- Hot flushes occur in over 50% of women entering the menopause and the frequency declines to 30% after three years. Symptoms may persist, however, in up to 16% of women at 67 years of age.
- The usual reason for prescribing hormone therapy (HT) is the treatment of vasomotor symptoms. The average patient is a woman aged 45 to 60 years, and the most common duration of use is less than three years.
- Estrogen with or without progestogen is an effective treatment for urogenital atrophy, but may worsen urinary incontinence.
- Estrogen and progestogen reduce risk of osteoporotic fractures of the hip, vertebrae, and other sites, but the effect on hip fracture is small, and HT treatment is not warranted solely for fracture prevention.
- Although estrogen was associated with a 34% reduction in the risk of senile dementia in epidemiological studies, the Women's Health Initiative Memory Study (WHIMS) failed to corroborate these observations.
- HT is not indicated for the primary or secondary prevention of coronary artery disease events. Alternative health strategies and pharmaceutical agents with established value should be used for primary prevention of coronary heart disease.

- Risk of venous thromboembolism is increased among women using estrogen/progestogen therapy (E/PT) and declines during continuing use. Route of administration may affect the magnitude of risk.
- E/PT treatment has a small but significant effect on breast cancer risk equivalent to eight new cases per annum per 10,000 women. The increased risk is seen after five years of current use and disappears several years after discontinuing therapy.
- Epidemiological studies suggest that there is a small but significant increased risk of epithelial ovarian cancer with unopposed estrogen use that is not observed when estrogen is combined with progestin. The effect is significant in women who take ET for 10 or more years.
- ET and E/PT are associated with side effects that include breast tenderness, vaginal discharge, and uterine bleeding.
- The current indications for ET and E/PT include the treatment of moderate to severe vasomotor symptoms, the treatment of vulvar and vaginal atrophy, and the prevention of osteoporosis.

## CLINICAL ALGORITHM(S)

None provided

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

#### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS.

The type of supporting evidence is not specifically stated for each recommendation.

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

## POTENTIAL BENEFITS

- Reduce symptoms resulting from estrogen depletion, including hot flushes, sleeplessness, lethargy, depressed mood, and vaginal dryness
- Treat urogenital atrophy
- Prevent osteoporosis

#### POTENTIAL HARMS

- Estrogen therapy (ET) and estrogen/progestogen therapy (E/PT) are associated with side effects that include breast tenderness, vaginal discharge, and uterine bleeding.
- Risk of venous thromboembolism is increased among women using estrogen/progestogen therapy (E/PT) and declines during continuing use. Route of administration may affect the magnitude of risk.
- E/PT treatment has a small but significant effect on breast cancer risk equivalent to eight new cases per annum per 10,000 women. The increased risk is seen after five years of current use and disappears several years after discontinuing therapy.

## QUALIFYING STATEMENTS

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While this document reflects appropriate management of a problem encountered in the practice of reproductive medicine, it is not intended to be the only approved standard of practice or to dictate an exclusive course of treatment. Other plans of management may be appropriate, taking into account the needs of the individual patient, available resources, and institutional or clinical practice limitations.

## IMPLEMENTATION OF THE GUIDELINE

## DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

**IOM CARE NEED** 

Getting Better Staying Healthy

IOM DOMAIN

Effectiveness Patient-centeredness

## IDENTIFYING INFORMATION AND AVAILABILITY

## BIBLIOGRAPHIC SOURCE(S)

Estrogen and progestogen therapy in postmenopausal women. Fertil Steril 2004 Jan; 81(1): 231-41. [75 references] PubMed

#### **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 Jan

# GUIDELINE DEVELOPER(S)

American Society for Reproductive Medicine - Private Nonprofit Organization

## SOURCE(S) OF FUNDING

American Society for Reproductive Medicine

#### **GUIDELINE COMMITTEE**

The Practice Committee of the American Society for Reproductive Medicine

#### COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

#### FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

#### **GUIDELINE STATUS**

This is the current release of the guideline.

#### **GUIDELINE AVAILABILITY**

Electronic copies: Available from the <u>American Society for Reproductive Medicine Web site</u>.

Print copies: Available from American Society for Reproductive Medicine, 1209 Montgomery Highway, Birmingham, Alabama 35216-2809; Phone: (205) 978-5000; Fax: (205) 978-5005; E-mail: <a href="mailto:asrm@asrm.org">asrm@asrm.org</a>; Web site: <a href="mailto:www.asrm.org">www.asrm.org</a>.

#### AVAILABILITY OF COMPANION DOCUMENTS

None available

## PATIENT RESOURCES

None available

## NGC STATUS

This NGC summary was completed by ECRI on August 23, 2004.

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